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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/857,797  | 09/13/2001  | John Walker          |                     | 9643             |
| 7590  | 12/03/2009  |                      | EXAMINER            |                  |
| JOHN WALKER<br>26 CHAPHAM STREET<br>BALWYN, VICTORIA, 3103<br>AUSTRALIA |             |                      | KIM, YUNSOO         |                  |
|   |             | ART UNIT             | PAPER NUMBER        | 1644             |
|   |             | MAIL DATE            | DELIVERY MODE       | 12/03/2009 PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/857,797             | WALKER, JOHN        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | YUNSOO KIM             | 1644                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 8/20/09.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 23-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 23-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/22/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

1. Claims 23-38 are pending and are under consideration.
2. Applicant's IDS filed on 4/22/09 has been acknowledged.
3. The following rejection remains.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 23-38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,228,262A, of record, in view of WO99/27959, of record, and U.S. Pat. No. 4,900,549, of record, for the reasons set forth in the office action mailed 2/17/09. The '262 application teaches a composition comprising a GnRH- diphtheria toxoid (DT) conjugate and an alum (aluminum hydroxide) as an adjuvant (claims 1-10). The '262 publication further teaches that GnRH is also known as LHRH (p. 1, line 21) and the composition comprising 20ug of GnRH-DT (p. 18).

The disclosure of the '262 publication differs from the instant claimed invention in that it does not teach the use of ionic polysaccharide (e.g. DEAE-dextran) and an immuno-stimulating complex comprising a saponin and a cholesterol as in claims 23-38.

The '959 publication teaches an adjuvant composition comprising a saponin and a DEAE-dextran (claims 1-22). The '959 publication teaches that the saponin is QuilA (Example 3), that said adjuvant composition improves adjuvanticity synergically (p. 2-3),

induces long lasting antibody responses and is suitable for use with various antigens (p. 7-8).

Moreover, the '959 publication teaches that a common vaccine formulation comprises an antigen and aluminum hydroxide gel (alum) as an adjuvant and there are some problems associated with this adjuvant. The alum adjuvant often fails to induce sufficient immune response and it is not acceptable for routine use because of inflammation, granulomas, ulceration and other lesions at the injection sites (p. 1-2, overlapping paragraph). The referenced adjuvant composition comprises saponin and DEAE-dextran enhances the effectiveness of an antigenic substance (p. 2).

Given that the mass ratio between the DEAE-dextran and saponin of about 125 is recited in claim 29, claim 29 is included in this rejection because the '959 publication discloses the upper range of saponin is 1mg/ml and the upper range of the DEAE-dextran is 150mg/ml (claims 14 and 16) which results in about 150 mass ratio. In light of this, claims 30, 31 and 35 reciting particular concentration of 10-100mg of DEAE-dextran and 80-800ug of saponin as the referenced concentrations of the saponin and DEAE-dextran are encompassed (claims 14 and 16).

The '549 patent teaches the addition of a cholesterol in adjuvant compositions comprising Quil-A and that the cholesterol stabilizes antigenic species and improves immunogenic activity (col. 1, lines 45- 68, col. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ and/or substitute alum adjuvant as taught by the '262 publication with an adjuvant composition comprising DEAE-dextran, saponin and cholesterol as taught by the '959 publication and the '549 patent.

One of ordinary skill in the art would have been motivated to do so because the adjuvant composition taught by the '959 publication and the '549 patent improves overall immune

response by providing an improved adjuvant activity. The Quil-A and DEAE-dextran adjuvant taught by the '959 publication enhances the effectiveness of an antigenic species in stimulating an immune responses to a much greater extent than alum adjuvant and the cholesterol stabilizes antigenic species and improves immunogenic activity.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references ad there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 8/20/09 have been fully considered but they were not persuasive.

Applicant has traversed the rejection based on that the combination of the reference is not obvious as it teaches away from using cholesterol. Applicant has asserted that the combination of the references may contain additional active components while currently amended claim reciting "consisting essentially of" does not contain additional active components. Applicant has further asserted that the '959 publication discloses DEAE dextran and saponin in the presence of mineral oil but does not mention use of cholesterol.

Contrary to Applicant's assertion, the currently amended limitation reciting "consisting essentially of" does not exclude other active components. The transitional phrase "consisting of" excludes any components not specified in the claim but "consisting essentially of" is construed as equivalent to "comprising". Moreover, the specification of the instant application does not define what is encompassed by active components. See MPEP 2111.03.

Further, Applicant's assertion that the combination of the references teaches away the use of cholesterol is misleading. Applicant has asserted that the '959 publication uses mineral oil as an essential adjuvant composition. Note that the '959 publication does not exclude cholesterol in the composition comprising a saponin. Rather, the '959 publication discloses the use of cholesterol with Quil A saponin (p.2, lines 14-16) and the '549 patent specifically teaches the use of cholesterol in the presence of Quil-A to stabilize antigenic species and improves immunogenic activities. Therefore, the combination of the references is obvious.

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

November 30, 2009

/Michael Szperka/

Primary Examiner, Art Unit 1644